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| 09/913,159      | 08/10/2001  | Michael Schreiber    | 35-213              | 3633             |

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07/13/2004

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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/913,159

## Applicant(s)

SCHREIBER, MICHAEL

## Examiner

Myron G. Hill

## Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1- 52 is/are pending in the application.
- 4a) Of the above claim(s) 1- 3, 9- 48, 53, and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4- 8, 26, and 49- 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/10/01, 1/22/02.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Applicant's election with traverse of Group II in the reply filed on March 30, 2004 is acknowledged. The traversal is on the ground(s) that the examiner has not meet the requirements for Lack of Unity. This is not found persuasive because applicant has not pointed out the supposed error in the Lack of Unity as presented in the previous action in which art was cited against the special technical feature of the product of claim 1.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1- 3, 9- 48, 53, and 54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This action is on claims 4- 8, 26, and 49- 52.

### ***Priority***

Applicant is requested to update the first line of the specification to indicate the status of this application as a National Stage entry of a PCT.

### ***Information Disclosure Statement***

Signed and initialed copies of the IDS papers filed 10 August 2001 and 22 January 2002 are enclosed.

### ***Sequence Requirements***

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This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on as follows:

The specification does not contain sequence identifiers (SEQ ID#s) in all locations where sequences are disclosed, see at least Figures 1, 2A, and 2B, and the descriptions of the figures in the specification. The figures contain sequences that are not identified by SEQ ID# in either the figures themselves or in the Brief Description of the Figures in the specification.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this Office Action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this Office Action will be held non-responsive.

### ***Claim Objections***

Claims 26, and 49- 52 are objected to because of the following informalities: they depend from non-elected claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4- 8, 26, and 49- 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to variable viral DNA molecules. It is not clear what part is variable, coding or non-coding sequence. Applicant should clarify that the variable nucleotides result in different translated when expressed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4- 8, 26, and 49- 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fomsgaard (Immunology Letters 1999, Vol. 65, pages 127- 131, from IDS) and Schreiber *et al.* (1997, Journal of Virology Vol. 71, pages 9198- 9205, from IDS) in view of Tartar ( 2 677 363, from IDS).

The invention is drawn to a DNA vaccine that contains over 100 different DNA molecules.

Fomsgaard teaches that DNA vaccines offer advantages over conventional vaccines (page 128, column 2, second paragraph).

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Fomsgaard does not teach DNA vaccines with 100 or more different sequences.

Schreiber *et al.* teach that V3 loop of HIV gp120 contains hypervariable regions and these contain many neutralizing epitopes (page 9198, paragraph spanning column 1-2). Schreiber *et al.* express the nucleotides in cells to produce peptides of the epitopes (Figure 3).

One of ordinary skill in the art at the time of invention would have known that Tartar teaches an example of the possible sequences in the hypervariable loop of gp120 of HIV (see the formula of claim 10). Knowing the importance of the variable amino acids as taught by Schreiber *et al.* one of ordinary skill in the art would have been motivated to use random and/or degenerate nucleotides or multiple plasmids to create sequences of the hypervariable region. One of skill in the art would know the different sequences of the V3 loop found in the different isolates of HIV and been able to create a table of possible sequences to use to create the variable sequences in the nucleotide vaccine. It would have been obvious to one of ordinary skill in the art to make this DNA vaccine product and to use it to express the nucleic acid in cells as done by Schreiber *et al.*

Thus, it would have been *prima facie* obvious to modify the vaccine of Fomsgaard using a range of V3 loop hypervariable loop regions as taught by Schreiber *et al.* with the expectation of success in making a vaccine that contains 1000 or more variants of the V3 loop hypervariable region.

### ***Conclusion***

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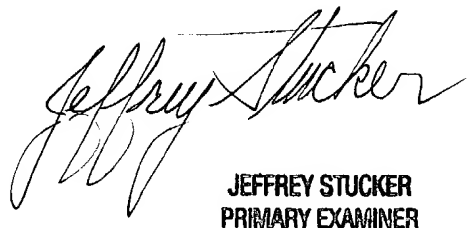
No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Myron G. Hill  
Patent Examiner  
1 July 2004



JEFFREY STUCKER  
PRIMARY EXAMINER